

**Notice of Allowability**

Application No.	Applicant(s)
09/686,499	CURTISS, ROY
Examiner	Art Unit
Khatol S Shahnan-Shah	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to applicant's response of 9/24/04.
2.  The allowed claim(s) is/are 1-22 and 45-46 renumbered 1-24 respectively.
3.  The drawings filed on 14 June 2004 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some\*    c)  None    of the:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached  
1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of  
Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

***Attachment to Notice of Allowance***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/24/04 has been entered.
2. Applicant's response and declarations under 37 C.F.R. 1.132, received 9/24/04 are acknowledged. The declarations are proper. They have been considered and entered. The declarations of Dr. Daniel A. Portnoy and Dr. Roy Curtiss III under 37 CFR 1.132 filed 9/24/04 are sufficient to overcome the rejection of claims 1-22 and 45-46 under 35 U.S.C. 102 (e), based upon evidence of teachings and arguments of one skilled in the art.
3. Claims 1-22 and 45-46 are pending and under consideration.

***Rejections Withdrawn***

4. Rejection of claims 1, 2, 8-13,16 and 21-22 under 35 U.S.C. 102, (e) made in paragraph 9 of the office action mailed 1/29/2002 is withdrawn in view of applicant's response and declaration.
5. Rejection of claims 1-7, 12-20 and 45-46 under 35 U.S.C. 102, (e) made in paragraph 8 of the office action mailed 12/16/2002 is withdrawn in view of applicant's response and declaration.

***Allowable Subject Matter***

6. Claims 1-22 and 45-46 are allowed. Claims are renumbered 1-24 respectively.

The following is an examiner's statement of reasons for allowance:

Claims are drawn to an attenuated derivative of a pathogenic microorganism, which comprises:

- (a) a non-functional native chromosomal essential gene;
- (b) a recombinant complementing gene on an extra chromosomal vector, wherein the complementing gene can recombine to replace the non-functional native chromosomal essential gene; and
- (c) a desired gene on the extra chromosomal vector, wherein the desired gene is a recombinant gene of (a), wherein the desired gene is stably maintained in a progeny population of the microorganism.

The prior art fails to teach the particular claimed invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

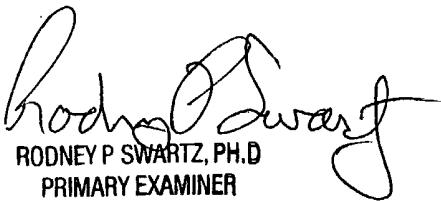
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645  
September 30, 2004

  
RODNEY P. SWARTZ, PH.D  
PRIMARY EXAMINER